

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of

SCOTT, et al.

Serial No.: 10/579,034

Filed: 3 October 2006

For: Diabetogenic Epitopes

Examiner Gerald R. Ewoldt

Group Art Unit: 1644

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Honourable Commissioner of Patent and Trademarks  
Washington, D.C. 20231  
U.S.A.

Sir:

## **DECLARATION OF AMANDA MACFARLANE UNDER RULE 37 CFR 1.132**

I, **Amanda MacFarlane**, hereby declare as follows:

1. I am co-inventor, along with Fraser W. Scott, Karolina Burghardt and Majid Mojibian, of the subject matter claimed in the application titled "Diabetogenic Epitopes". This application was filed in the United States Patent and Trademark Office on October 3, 2006 as the national phase of PCT/CA05/00025 filed January 10, 2005 and claiming priority to U.S. provisional application 60/535,278 filed January 9, 2004.

2. Background of **Amanda MacFarlane**

BSc, Honours in Biology and Biotechnology, Carleton University (2000)

PhD, Biochemistry, University of Ottawa (2004)

Post-Doctoral Research Fellow, Division of Nutritional Sciences, Cornell University (2004-2007)

Research Associate, Division of Nutritional Sciences, Cornell University (2007-2008)

Research Scientist, Nutrition Research Division, Health Canada (2008-present)

Adjunct Professor, Dept. Biochemistry, Microbiology and Immunology, University of Ottawa (2009-present)

Adjunct Professor, Dept. Biology, Carleton University (2010-present)

3. Examiner Ewoldt issued an Office Action March 26, 2010 wherein MacFarlane et al., (2003) "A Type 1 Diabetes-related Protein from Wheat (*Triticum aestivum*); cDNA clone of a wheat storage globulin, Glb1, linked to islet damage" Journal of Biological Chemistry Vol. 278, No. 1, pp. 54-63, (hereinafter "MacFarlane") was cited under 35 USC 102(b) in rejecting claims 1, 2 and 4. Examiner Ewoldt indicated that MacFarlane teaches a Glb1 isoform, the protein expressed from clone WP5212, comprising the EEQLRELRRQ amino acid sequence of SEQ ID NO:1. Examiner Ewoldt further indicated that the reference further teaches the protein attached to a support.
4. Examiner Ewoldt issued a further Office Action November 19, 2010 wherein MacFarlane was cited in rejecting claims 1 and 4 under 35 U.S.C. 102(b). MacFarlane was also cited in rejecting claim 3 under 35 U.S.C. 103(a).
5. I am one of the co-authors of MacFarlane.
6. The MacFarlane reference does not disclose the EEQLRELRRQ amino acid sequence of SEQ ID NO:1 of the clone internally referred to as WP5212.
7. The reference WP5212 was an internal reference and mention of it in the MacFarlane publication does not allow one skilled in the art to obtain the WP5212 clone, nor does it allow one skilled in the art to obtain the sequence listing of the diabetogenic epitope sequence EEQLRELRRQ (SEQ ID NO: 1) contained in clone WP5212 without access to the clone WP5212.
8. Neither the clone referred to as WP5212 nor the DNA or amino acid sequence thereof was publicly available before January 9, 2004. As the clone was not made available to the public for analysis before January 9, 2004, mention of the clone referred to as WP5212 in the MacFarlane publication does not allow one skilled in the art to obtain the sequence listing of the amino acid sequence of the WP5212 clone.

9. The first publication of the amino acid sequence EEQLRELRRQ referred to as SEQ ID NO:1 from the clone referred to as WP5212 was in PCT/CA05/00025 published July 21, 2005.
10. I declare that all statements made herein are of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of the present application or any patent issuing thereon.

EXECUTED at Ottawa ON this 15 day of April, 2011.

By   
Amanda MacFarlane